REMARKS

The March 14, 2005 Official Action and the reference cited therein have been carefully reviewed. In view of the amendments presented herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, Applicants note that the Examiner has deemed the restriction requirement proper and has made it final. Accordingly, claims 4, 7, 9-15, 25-29 and 33-34 are withdrawn from consideration and claims 1-3, 5, 6, 8, 16-24, and 30-32 have been examined on the merits.

At page 5 of the Official Action, the Examiner has objected to the specification and claim 24 as containing certain minor informalities. The informality in claim 24 has been corrected in accordance with the present amendment, thereby rendering this objection moot. Applicants respectfully submit that the disclosure does not contain an embedded hyperlink or another form of browser executable code as asserted by the Examiner at page 5 of the Official Action. The http:// portion of the link has been omitted and therefore it is not browser executable. Accordingly, Applicants have not amended the specification to remove these partial web site listings.

Claims 1-3, 5,6, 8, 16-24 and 30-32 stand rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in such a way as to convey to the skilled artisan that applicants were in possession of the invention at the time the application was filed.

The Examiner has further rejected claims 1-3, 5,6, 8, 16-24 and 30-32 under 35 U.S.C. §112, first paragraph

asserting that undue experimentation is required to practice the full scope of the claims.

At page 13 of the Official Action, the Examiner has rejected claims 1, 3, 5, 6, 8, 16-22 and 30-32 under 35 U.S.C. §102(b) as allegedly anticipated by the disclosure in Kamada et al.

Applicants respectfully submit that the claims as presently amended are in condition for allowance. Each of the above-noted objections and rejections under 35 U.S.C. §112, first paragraph and §102 is, therefore, respectfully traversed.

CLAIMS 1-3, 5,6, 8, 16-24 AND 30-32 AS AMENDED FULLY SATISFY THE WRITTEN DESCRIPTION REQUIREMENTS OF 35 U.S.C. §112, FIRST PARAGRAPH

Applicants strenuously disagree with the position taken by the Examiner in the March 14, 2005 Official Action. At the outset, Applicants take exception to the Examiner's contention that given the definitions provided in the present application, a VRN1 sequence can read on a single codon of that sequence. This interpretation fails to take into account the functional limitation of the claim language requiring that the VRN1 encoded polypeptide be capable of altering a vernalization response in a plant. Clearly, a codon would not satisfy this functional limitation.

Applicants also submit that the Examiner's assertion that Applicants have not identified any essential regions of any VRN1 nucleic acid encoding any peptide which is capable of altering the vernalization response in a plant is erroneous. In Example 8, a detailed analysis of the

VRN1 protein is disclosed including elucidation of

1) putative B3 DNA binding domains, including phylogenic and physiochemical analysis thereof;

2) nuclear localization signals;

3) PEST regions, one of which contains a potential PKC phosphorylation site, which may affect cellular life span;

4) RXXL motifs;

and

5) a linker region.

Methods for assessing the vernalization response are provided at page 5. The existence and sequence of a closely related Arabidopsis gene is provided in Example 8c) at page 52. Page 12 provides a list of similar genes and which share high levels of sequence similarity with VRN1.

In light of the foregoing disclosure, the functional limitation of the claim and the provision of SEQ ID NO: 11 encoded by SEQ ID NO: 10, Applicants submit the essential portions of the VRN1 polypeptide have been described to the skilled person.

As noted in the MPEP at § 2163,

> To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

Applicants have canceled claim 1 and amended claim 2 such that it is now in independent form and recites a homologous variant which shares at least 90% identity with the sequence encoding SEQ ID NO: 11. The Examiner contends that Applicants have not provided a sufficient number of species to claim the genus of nucleotide sequences having

at least 50, 60, 70, 80 or 90% sequence identity to disclosed sequences encoding a VRN1 polypeptide.

Applicants respectfully disagree with the Examiner's position. However, in an effort to expedite prosecution of the instant application, Applicants have removed reference to nucleotide sequence having at least 50%, 60%, 70% or 80% identity to the sequence encoding SEQ ID NO: 11 and have amended the claims to recite those sequences which share at least 90% or higher identity with the recited sequence. Accordingly, Applicants submit that claim 2 and those claims which depend from it are directed to a more narrowly defined genus of sequences. Applicants submit that the skilled person would readily appreciate that the present inventors had possession of the reference sequence, SEQ ID NO: 10 encoding a polypeptide of SEQ ID NO: 11 and homologous variants which are greater than 90% identical thereto which also modulate the vernalization response in higher plants.

In summary, Applicant **does** disclose essential regions of VRN1, **does** disclose sequences sharing high levels of identity or are capable of hybridizing to VRN1 nucleic acid under highly stringent conditions. The totality of the disclosure does support the scope of the claims as amended, none of which are defined in purely functional terms. In light of all the foregoing, Applicants request that the rejection of claims 1-3, 5,6, 8, 16-24 and 30-32 for inadequate written description be withdrawn.

CLAIMS 1-3, 5,6, 8, 16-24 AND 30-32 AS AMENDED ARE FULLY ENABLED BY THE SPECIFICATION AS FILED

Applicants vigorously dispute the Examiner's

contention that the present invention has not been reduced to practice. The effects of VRN1 nucleic acid and mutations have been studied and are known to affect the vernalisation response in wild type plants, and to complement the phenotype in a mutant background.

Contrary to the Examiner's position, Applicants **have** taught how to generate a plant with altered vernalisation phenotype, both by way of specific example (see above) and generic disclosure (see specification pages 19-26). They have also taught how such plants can be used (see specification pages 3-4). They have also taught how to isolate homologous sequences of the sort encompassed by the claims, and indeed have exemplified several such sequences.

The Examiner has offered no well founded reasons for doubting that the nucleic acid would not work as suggested in other plant backgrounds into which it was introduced. In In re Wands, 8 USPQ2d 1400 (1988), cited by the examiner, the Federal Circuit Court of Appeals held that engagement in experimentation to practice a claimed invention does not render the disclosure non-enabling as long as the experimentation required is not "undue". The Court stated that: "The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness...The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed" In re Wands, 8 USPQ2d 1400, 1404 (1988).

In the present case, the experimentation necessary is merely routine and is inherent in the nature of the art.

Therefore, there is no undue burden of experimentation and the claimed subject matter is enabled.

The Examiner objects, in essence, that functional variants of VRN1 are not enabled, and refers to Bowie *et al.* Bowie teaches that "proteins are surprisingly tolerant of amino acid substitutions" (page 1306, right column). Accordingly, the skilled person can readily obtain variants by, for example, mutagenesis of the amino acid sequence. The skilled person can ensure production of a functional variant by testing the mutant sequences for function. If, by chance, mutagenesis does destroy protein function, then the nucleic acid is outside the scope of the claim. As noted above, a claim may be patentable even if some experimentation is required, so long as the experimentation is not undue. In the present case, well-known techniques are available for identifying the claimed variants, and no undue experimentation is required. Non-functional mutants will be relatively rare, and can in any case be discarded following testing for activity. Therefore, the claimed subject matter is enabled.

The Examiner's attention is also respectfully drawn to In re Angstadt and Griffin, 190 USPQ 214 (CCPA 1976) wherein the Court held that an applicant need not demonstrate the operability of each and every species covered by a claim and that patentable claims may cover inoperable species. In the present situation, the skilled person knows how to ensure successful operation of the claimed methods and can readily find embodiments in which the compositions and methods will function as claimed, so that occasional failure of the methods does not mean that the claim as a whole is non-enabled.

To gain a reasonable protection for the invention, the

applicant should be allowed claims that cover the disclosed sequence plus very similar variants. It is well known that conservative substitutions can be made in a protein by changing the encoding nucleic acid so that a different but similar amino acid is inserted in the polypeptide sequence. Sometimes, such a point mutation destroys the function of the protein, but this is rare and non-functional variants are excluded by the functional limitation in the claim. Normally, a point mutation has no significant effect on function (See Bowie, cited by Examiner). Therefore, the skilled person can readily envisage variants of the sequences provided that would be fully functional but that would have a slightly different sequence to the one shown in the application. The applicant should reasonably be allowed to protect such simple sequence variants.

At page 13 of the Official Action, the Examiner asserts that even if Applicant were successful in arguing the issues set forth, Applicant is still limited to nucleotides 269-1295 of SEQ ID NO: 10 encoding SEQ ID NO: 11. On what statutory basis is the Examiner relying on when making this assertion?

Applicants submit that the claims as amended are fully enabled by the specification as filed. Accordingly, Applicants request that the rejection of claims 1-3, 5,6, 8, 16-24 and 30-32 under 35 U.S.C. §112, first paragraph be withdrawn.

CLAIMS 1-3, 5,6, 8, 16-24 AND 30-32 ARE NOVEL OVER KAMADA ET AL.

In order to constitute evidence of lack of novelty under 35 U.S.C. §102(b), a prior art reference must

identically disclose each and every element of the rejected claim. In re Bond, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). Applicants submit that Kamada et al. do not disclose a VRN1 nucleotide or its encoded protein which is identical to that presently claimed as this reference is relates to a RolC encoding nucleic acid which is not SEQ ID NO: 10 nor is it 90% identical to SEQ ID NO: 10. Accordingly, Applicants request that the rejection of the above-identified claims on this basis be withdrawn.

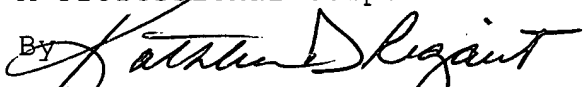
CONCLUSION

No new matter has been introduced into this application by reason of any of the amendments presented herewith. In view of the present claim amendments, and the foregoing remarks, it is respectfully urged that the rejections set forth in the March 14, 2005 Official Action be withdrawn and that this application be passed to issue. In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned attorney at the phone number given below.

Respectfully submitted,

DANN, DORFMAN, HERRELL AND SKILLMAN

A Professional Corporation

By 

Kathleen D. Rigaut, Ph.D., J.D.

PTO Registration No. 43,047